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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,874	08/20/2003	Kenneth F. Buechler	36671-744.502	8658

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Inverness Medical Innovations / WSGR
Wilson Sonsini Goodrich & Rosati, P.C.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,874	BUECHLER ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/24/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29, 32, 43 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng *et al.*, J. Am. Coll. Cardiol., vol. 37, pp 386-391 (2001) ("Cheng") in view of U.S. Patent Application Publication No. 2004/0167341 to Haffner *et al.* ("Haffner").

i. Claims 29, 32 and 43 are obvious

Cheng describes a "BNP guided treatment" regimen for congestive heart failure. Page 390, right column, first and second paragraphs. The regimen uses BNP measurements as an indicator to adjust medication for patients with the disease. *Id.* The regimen provides effective care while reducing invasive hemodynamic monitoring. *Id.* With this description, Cheng teaches the "selecting," "performing" and "determining" steps claimed.

Cheng, however, does not teach the "administering" step.

.Haffner describes administering an inhibitor of DPP-IV for treating congestive heart failure. *See* page 3, paragraphs 0028 and 0030.

With the foregoing description, one of ordinary skill in the art would have found it obvious to modify Cheng's method by adding Haffner's technique of treating congestive heart disease with a DPP-IV inhibitor. The skilled artisan would have been motivated to make the modification because Cheng's method includes a suggestion to treat congestive heart failure and Haffner's method provides a specific treatment regimen for accomplishing Cheng's suggestion. Indeed, because both references are directed to congestive heart failure, the skilled artisan would have had a reasonable expectation of success in combining them.

ii. Claims 47-49 are obvious

Claims 47-49 are dependent on claims 29, 32 or 43 and taught by Cheng, which describes a fluorescence immunoassay to test for BNP. *See* page 387, right column, first paragraph.

Claims 30 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng in view of Haffner, both cited above, as applied to claim 29, and further in view of De Meester *et al.*, Biochemical Pharmacology, vol. 54, pp. 173-179 (1997) ("De Meester").

Cheng and Haffner do not teach a dipeptide analogue comprising a phosphonate moiety.

De Meester describes a method of using prodipine (pro-pro-diphenyl-phosphanate) to block DPP-IV activity. *See* page 178, left column, second to third full paragraphs. Prodipine acts in both plasma and tissue, providing long-lasting results and functions without affecting any other enzyme or producing adverse effects upon the patient.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cheng and Haffner's method by administering prodipine. The skilled artisan would have been motivated to make the modification because De Meester indicates that prodipine is long-lasting and poses no adverse affects on a person. Moreover, because prodipine is a type of DPP-IV inhibitor, the skilled artisan

would have had a reasonable expectation of success in combining this compound with Cheng and Haffner's method.

Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng and Haffner, both cited above, in view of U.S. Patent No. 6,756,483 to Bergmann *et al.* ("Bergmann").

Cheng and Haffner do not teach prolyl-specific DPP inhibitors that comprise an antibody.

Bergmann states that an inhibitor to DPP-IV can be any suitable selective binder, antibody or similar receptor molecules. *See* column 3, lines 35-42.

The Federal Circuit and the Board of Patent Appeals and Interferences have ruled that art-recognized equivalence presents a strong case for obviousness, where one material can be substituted for another. *See* MPEP 2144.06, citing the *In re Ruff* and *Smith v. Hayashi* cases:

> In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); ** Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.).

Here, Bergmann explicitly states that a selective binder, an antibody and similar receptor molecule are all appropropriate inhibitors of DPP-IV. Haffner describes As a receptor molecule, pyrrolidine is an art-recognized equivalent to an antibody when it comes to inhibiting DPP-IV. Applicants have not provided evidence to the contrary. Accordingly, the skilled artisan would have found it obvious to modify Cheng and Haffner's method by substituting the pyrrolidine taught by those references with the antibodies taught by Bergmann. Moreover, for the same reasons, the skilled artisan would have had a reasonable expectation of success in making the modification.

Claims 33 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng in view of Haffner, both cited above, as applied to claim 29, and further in view of Mills *et al.*, Journal of the American College of Cardiology, vol. 34, no. 1, pp. 155-162 (1999) ("Mills").

Cheng and Haffner do not teach the step of administering natriuretic peptides to the subject.

Mills describes a method for administering Nesiritide, a human B-type natriuretic peptide. *See* page 155, entire page. Nesiritide can maintain hemodynamic effects for patients with symptomatic decompensated heart failure. *Id.*

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cheng and Haffner's method by including an administration of Nesitiride. The skilled artisan would have been motivated to make the modification based on Mill's disclosure that Nesitiride provides some benefit for patients with

decompensated heart failure. Moreover, the skilled artisan would have recognized that because DPP-IV inhibitors and Nesitiride would act in concert to treat congestive heart failure, the two compounds can be administered together. Accordingly, the skilled artisan would have had a reasonable expectation of success in combining the references.

Response to Arguments

Applicants traverse the prior art of record in the response filed March 18, 2009. *See* pages 5-10, alleging that the prior art does not anticipate or render obvious the present claims. Applicants' arguments have been considered but are moot in view of the new ground of rejection. See supra, the rejection of claims 29-49.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

/Nelson Yang/
Primary Examiner, Art Unit 1641